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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,801	01/11/2002	Jackie Y. Ying	M00925/70110	4734

23628 7590 02/05/2003

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EXAMINER

KOSLOW, CAROL M

ART UNIT	PAPER NUMBER
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1755

12

DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,801

Applicant(s)

YING ET AL.

Examiner

C. Melissa Koslow

Art Unit

1755

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 581-673 is/are pending in the application.
- 4a) Of the above claim(s) 640-673 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 581-639 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

The amendment filed 31 May 2002 proposes amendments that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required with the next office action.

Newly added claims 581-673 were not underlined.

The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 6,013,591 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

The starred references on the Information Disclosure Statement of 3 June 2002 have been considered but have been lined out. This was done to prevent confusion for the printer since the printer interprets starred documents as not to be printed and initial documents to be printed. It is requested that applicants resubmit the PTO-1449 but without the stars so the Examiner can initial the documents.

Newly submitted claims 640-673 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 640-660 and claim 581 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, that the product as claimed can be made by another and materially different process such as a sol-gel process or a precipitation process that does not contain an aging step.

The method of claims 661-673 and claims 586 and 597-639 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and the product produced by the claimed method does not have the properties required in the claimed articles.

Claims 581-585 and 595-596 and claims 661-673 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, product as claimed can be used in a materially different process of using that product, such as a bone filler.

These method claims are not considered original patent claims even though claims to the subject matter of claims 640-673 were present in the original patent because applicants canceled those claims in a preliminary amendment and thus they were not examined.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 640-673 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03 and 1450.

Claims 581-639 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

Applicants added the limitations that the apatite crystals in the particulate are spherical and that the average apatite crystal size is less than 100 nm to obtain the original patent. Since the newly presented claims do not include the crystal shape limitation and includes average crystal sizes that are 100 nm and greater, the new added claims are broader than the patent claims

Art Unit: 1755

and since the limitations now being omitted or broadened in the present reissue were originally presented and argued in the original application to make the claims allowable over a rejection made in the original application, the omitted limitations in the newly added claims relate to subject matter previously surrendered by applicant, and impermissible recapture exists. See MPEP 1412.02.

Claims 581-583, 595, 596 and 613 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows:

There is no teaching or suggestion in the original patent that the particulate apatite comprises an organic species, such as a self-assembling surfactant or a polymer. There is no teaching in the original patent that the surface area is “at least about 40 m²/g”, “at least about 60 m²/g”, or “at least about 100 m²/g”. The original patent only teaches the surface area is at least 40 m²/g, at least 60 m²/g, or at least 100 m²/g.

Claims 581-583, 595, 596 and 613 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

There is no teaching in the specification that the surface area is “at least about 40 m²/g”, “at least about 60 m²/g”, or “at least about 100 m²/g”. The specification only teaches the surface area is at least 40 m²/g, at least 60 m²/g, or at least 100 m²/g. There is no teaching or suggestion in the specification that the particulate apatite comprises an organic species, such as a self-assembling surfactant or a polymer. Column 10, lines 42-45 teach a composition comprising

Art Unit: 1755

particulate apatite and a polymer or a self-assembling surfactant. This teaching does not support the claimed particulate apatite comprises an organic species, such as a self-assembling surfactant or a polymer, since the surfactant and the polymer are part of the apatite particulates.

Claims 617, 618, 629 and 630 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for load bearing dental or orthopedic implants, does not reasonably provide enablement for any dental or orthopedic implant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The claims recite dental or orthopedic implant. This encompasses any dental or orthopedic implant. However, the specification only teaches in column 9, lines 64-65 the use of load bearing dental or orthopedic implants. Such a limited disclosure does not support the breadth of the instant claims. The examiner suggests the incorporation of "load bearing".

Claims 612 and 638 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for implants having a reactive layer composed of nanocrystalline carbonated apatite, does not reasonably provide enablement for any article comprising densified carbonated apatite having a dimension of at least 0.5 cm. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The claims recite an article comprising densified carbonated apatite having a dimension of at least 0.5 cm. This encompasses any article. However, the specification only teaches in example 12 an implant having a reactive layer composed of nanocrystalline carbonated apatite. Such a limited disclosure does not support the breadth of the instant claims.

Claims 581-596 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “at least about” is invalid for indefiniteness since there is nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term “about.” *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 581, 584 and 585 are rejected under 35 U.S.C. 102(b) as being anticipated by the commercially available Aldrich composition taught in Table 2 and discussed in example 2.

Example 2 and Table 2 teaches the composition comprises apatite particulates having a crystal size of 92 nm and a surface area of 39.5 m²/g. Thus the average apatite particle and crystal size falls within the claimed ranges. The taught surface area falls within the claimed range since 39.5 is “about 40”. The claimed composition reads upon that taught.

Claims 581-586 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagai et al, U.S. Patent 4,497,075 or U.S. patent 4,429,691.

These references teach compositions comprising densified particulate apatite. The examples in U.S. patent 4,429,691 and U.S. Patent 4,497,075 teach apatite particulates having an average particle and crystal size range of about 20-100 nm. These ranges fall within the claimed

Art Unit: 1755

ranges. Nagai et al teach apatite particulates having an average particle and crystal size range of about 5-90 nm. These ranges fall within the claimed ranges. While the surface area for these particulates are not taught, one of ordinary skill in the art would expect them to have a surface area range that falls within that claimed, absent any showing to the contrary, since the particles ranges falls within the claimed range. The references teach the claimed composition.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 586 is rejected under 35 U.S.C. 103(a) as being unpatentable over the commercially available Aldrich composition taught in Table 2 and discussed in example 2.

As discussed above, this powder reads upon that taught. It is notoriously well known to densify apatite powder composition to form implants or as a bone filler material. Thus one of ordinary skill in the art would have found it obvious to densify the commercially available Aldrich composition taught in Table 2 and discussed in example 2.

Claims 620, 622, 623 and 626-630 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jarcho.

This teaches apatite articles having an average XRD crystal size range of 200 nm to 3 microns, a density greater than 98% and a compression strength of about 90,000-150,00 psi or about 620-1034 MPa. These articles can be prosthesis, a coating for prosthesis or dental implants, all of which have a dimension of at least 0.5 cm. The density and strength and dimension fall within the claimed ranges and an average XRD crystal size range that overlaps the

Art Unit: 1755

claimed range. Product claims with numerical ranges which overlap prior art ranges were held to have been obvious under 35 USC 103. *In re Wertheim* 191 USPQ 90 (CCPA 1976); *In re Malagari* 182 USPQ 549 (CCPA 1974); *In re Fields* 134 USPQ 242 (CCPA 1962); *In re Nehrenberg* 126 USPQ 383 (CCPA 1960). The reference suggests the claimed article.

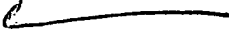
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Koslow whose telephone number is (703) 308-3817. The examiner can normally be reached on Monday-Friday from 8:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell, can be reached at (703) 308-3823.

The fax number for Amendments filed under 37 CFR 1.116 or After Final communications is (703) 872-9311. The fax number for all other official communications is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661 or (703) 308-0662.

cmk
January 28, 2003


C. Melissa Koslow
Primary Examiner
Tech. Center 1700